



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/397,548	09/16/99	BROWN	J A0000166-66-

WARNER-LAMBERT COMPANY  
2800 PLYMOUTH ROAD  
ANN ARBOR MI 48105

HM22/0813

EXAMINER

PAK, M

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED:

08/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/397,548**

Applicant(s)  
**Brown et al.**

Examiner  
**Michael Pak**

Art Unit  
**1646**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 1, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other:

## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election with traverse of Group VI, claims 13-15, drawn to human polypeptide, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Group V and VI are classified in same class and subclass. This is not found persuasive because porcine and human polypeptide are structurally different and require separate sequence search.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Objections*

2. Claims 14 and 15 are objected to because of the following informalities. Appropriate correction is required.

Claims 14 and 15 recite "SEQ ID n<sup>o</sup>" which appears to be a misspelling of SEQ ID NO:.

Claims 14 and 15 recite porcine sequences which belong to non-elected group.

3. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising of SEQ ID NO:14-17, does not reasonably provide enablement for an isolated polypeptide comprising the amino acid sequence of a secreted soluble  $\alpha 2\delta$ -1

polypeptide or an isolated polypeptide comprising the amino acid sequence with at least 80% identity to the SEQ ID NO:14 or a sequence complementary thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 13 encompass any recombinant polypeptide which may be a variant or fragment of a secreted soluble  $\alpha 2\delta$ -1 polypeptide. Claim 14 encompass an isolated variant with 20% sequence difference including non functional polypeptide. Claim 14 recite "a sequence complementary thereof" which is not enabled because one skilled in the art cannot make proteins which are complementary in sequence. Furthermore, claims encompass a large genus of variants which are not functional. One skilled in the art cannot predict the variants which are functional and non-functional. No guidance or working examples are provided to guide the skilled artisan in selecting the appropriate variants which would result in functional versus non-functional protein. A vast number of variant sequences would have to be screened in order to determine the functional protein and thus require undue experimentation.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs

Serial Number: 09/397,548  
Art Unit: 1646

3

of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Harpold et al. (US 5,429,921).

Harpold et al. disclose polypeptides comprising SEQ ID NO:25 amino acid sequences which are 100% identical to claimed SEQ ID NO: 14-17.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*

Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
8 August 2001